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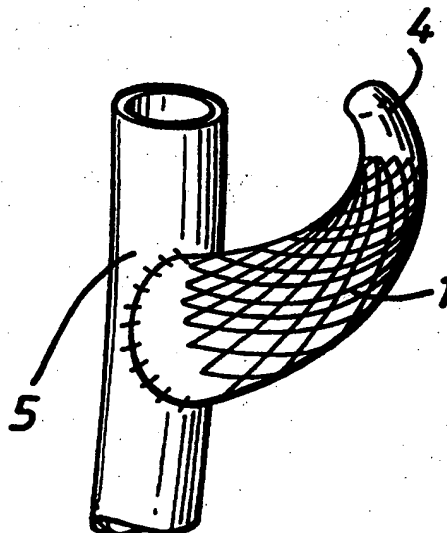
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(54) Title: STENTS FOR BLOOD VESSELS

(57) Abstract

A stent for supporting part of a blood vessel which stent includes a supporting portion around which or within which part of a blood vessel intended for grafting can be placed so that the stent internally or externally supports that part and the supporting portion of the stent is of a shape and/or orientation whereby flow between graft and host vessel is caused to follow a non-planar curve. By maintaining non-planar curvature in the graft itself, favourable blood flow velocity patterns can be achieved through generation therein of 'swirl' flow. Failures in such grafts through blockage, kinking or collapse, can be significantly reduced.



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STENTS FOR BLOOD VESSELS

This invention is concerned with stents for supporting parts of blood vessels. More particularly it is concerned with stents such as supporting devices for arterial or venous grafts.

Stents are known devices used in surgery especially in vascular surgery for providing physical support to a blood vessel i.e. they can be used to help prevent kinking and/or collapse of blood vessels such as veins or arteries.

It has been proposed that vascular prostheses may incorporate non-planar curvature to improve blood flow velocity patterns by skewing the motion to induce 'swirl' flow to the blood circulating through the prosthesis.

We have now devised an apparatus and technique for establishing and/or maintaining non-planar curvature within arterial and/or venous grafts e.g. in blood vessel bypass surgery wherein the graft is a donor part from another blood vessel from the patient, which part is to be surgically connected to create a bypass in a blocked, constricted or otherwise blood flow-restricted vessel.

By maintaining non-planar curvature in the graft itself, favourable blood flow velocity patterns can be achieved through generation therein of 'swirl' flow. Failures in such grafts through blockage, kinking or collapse, can be significantly reduced.

According to this invention there is provided a stent for supporting part of a blood vessel which stent includes a supporting portion around which or within which part of a blood vessel intended for grafting can be placed so that the stent internally or externally supports that part and the supporting portion of the stent is of a shape and/or orientation whereby flow between graft and host vessel is caused to follow a non-planar curve.

The supporting portion of the stent may be fabricated to incorporate:

- (i) a non-planar curved form and/or

(ii) a geometric arrangement of the junction between graft and host vessel e.g. artery whereby the tangent vector from the centreline of the graft does not intersect the centreline of the host vessel by consequence of an asymmetric disposition of the graft with respect to that host vessel at the junction with the graft.

The stent may be of generally hollow tubular shape with three dimensional curvature. The stent is particularly preferred for use in supporting such blood vessel parts as arterial and venous grafts, such as the living donor vessels used in bypass surgery.

The stent may take the form of an open lattice generally tubular framework with discrete openings at each end thereof.

A blood vessel part such as an arterial graft may be passed through the interior section of e.g. a partially coiled tubular stent, which stent then provides support for that part of the graft which passes through its interior, and which thereby imparts to that graft a geometry which includes non-planar curvature i.e. the vessel part supported by the stent can assume and maintain curvature which is non-linear. Part of the supported vessel in such embodiments thereby acquires a geometry which can be regarded as a partial helical curve even if the physical extent of the supported vessel is less than one complete turn of a helix e.g. less than $\frac{1}{2}$ or less than $\frac{1}{4}$ of such a turn.

In other embodiments of the invention, the stent can comprise a first supporting structure adapted to support or otherwise contact part of the vessel to be bypassed, with a secondary supporting structure attached to and extending away from the first supporting structure, but simultaneously supporting the arterial or venous graft. The secondary such supporting structure may, for example, comprise a plurality of elongate members linked or connected in the region of their ends remote from the first supporting structure.

Such elongate members can be fabricated such that between them they define a curved section wherein the

curvature is non-planar. Such an arrangement is particularly suited to an external stent for supporting the graft vessel at either or both physical junctions of the graft, as in a typical venous or arterial graft sites.

A practical embodiment of a non-planar internal stent is one fabricated from a shape memory alloy, formed to adopt an appropriately helical or part-helical form, to provide the required support for the graft after insertion.

In order that the invention may be illustrated, more easily understood and readily carried into effect by one skilled in this art, reference will now be made to the accompanying drawings of preferred embodiments by way of non-limiting example only, and in which:

Figures 1a to c depict an embodiment of an external stent shaped to conform the graft part in non-planar curvature at a site of arterial graft,

Figure 2 shows an alternative embodiment of an external stent,

Figure 3 shows a configuration of artery with a graft vessel attached tangentially to the arterial wall,

Figure 3a is a side view of the Figure 3 arrangement,

Figure 4 shows one suitably shaped external stent adapted to establish and maintain non-planar curvature in an arterial graft part as shown in Figures 3 and 3a,

Figure 4a is a side view of the Figure 4 supported graft site,

Figure 5 is an alternative embodiment of an internal stent based on a clip of e.g. shape memory alloy,

Figures 6a and 6b show a part-helical internal stent,

Figure 6c shows the stent of Figures 6a/6b internally supporting an arterial graft part,

Figure 7a shows a bypassed artery, an externally located stent for the graft and a sensor for transmitting flow data, and

Figure 7b shows a similar arrangement to figure 7a

but wherein the sensor is located around the supported graft part.

Referring to figures 1a to c of the drawings, the device shown may be fabricated from a thermosettable plastic, in the form of a hollow tube, the walls of which contain numerous openings so that the exterior of the graft is not fully shielded.

In particular, figure 1(a) shows the stent before thermosetting, whereas figure 1(b) and (c) indicate possible configurations whereby prior thermosetting has rendered this stent to adopt the shape of a partially coiled, non-planar curve.

The stent is then inserted over the graft to ensure the geometrical configuration of graft and host vessels, e.g. arteries adopt a predetermined form in the locality of the graft.

The stent may be of constant diameter, or tapered, as in figure 1(a) to accommodate the common practice of enlarging the graft in the vicinity of its junction with the host artery. The stent may be fixed to the graft by sutures (shown arrowed) or to avoid trauma to the graft, may be attached to a clip ring placed about the host vessel.

The restraining action of the stent may be graduated, by mechanically "tapering" the rigidity of the material: for example, at either end, material may be removed or the rigidity reduced by cuttings. An internally locatable stent is also provided which corresponds to the external stent just described, however such a stent is inserted into the interior of the graft vessel part rather than being placed exterior to the graft.

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Referring to figure 2 the non-planarity of the graft 4 is attained by supporting it with an external stent 1, 2 which comprises a longitudinal part section 1 of a cylinder, fabricated of a suitable porous biocompatible material, which may be of straight or curved section, to support that part of the artery 5 in the region of the graft, and integral with part section 1, or attached securely thereto are a plurality of elongate external support members 2, which are fabricated to define an internal region 7 of appropriate non-planar geometry.

The ends 6 of the support members 2 may be secured in situ by surgical thread (not shown) or by a fastening ring 3. The grafted vessel 4 is located within that internal region 7.

Figures 3 and 3a depict a non-planar configuration of graft and artery wherein an arterial graft (artery 5, graft 4) having a non-planar curve is surgically attached offset to the central portion of the artery 5 in that it is at least partly tangential to the artery, see the direction of flow arrow in figure 3a.

The external stent (1,2) of Figure 2 can be modified to support and maintain the non-planar curvature of the graft in the Figure 3/3a arrangements, by for example the structure as depicted in Figures 4/4a. Figures 4 and 4a have reference numerals which correspond with those used in figure 2 described above.

As shown in Figure 5 an internal stent for establishing and/or maintaining non-planar curvature of a graft (vessel part) comprises a clip 8 which is part coiled or at least part helical of shape memory alloy, affixed to a cylindrical wire mesh 9.

Figures 6A and 6B show an alternative embodiment of an internal stent, in which the stent 1 is fabricated from a linked wire mesh of part helical form. The material used is preferably a shape memory alloy to facilitate insertion of the stent. Figure 6C shows the stent located in the graft post insertion. The graft 4 surgically attached to artery 5

has been shown 'transparent' for purposes of illustration, to show the internally located, part helical wire mesh stent in-situ.

Referring to Figures 7A and 7B, either internal or external stents may incorporate devices which assist in monitoring the condition of either the graft or the host vessel or both.

In one possible embodiment shown in figure 7A, an external stent 1 incorporates a sensor portion 10 for monitoring the condition of the host artery. The sensor portion is a ring placed over the host artery 5, attached to the tubular stent 1 placed over the graft. The sensor and stent may be secured together by means of clips or threads during the operation to insert the graft. The sensor 10 may incorporate one or several ultrasound probes, or it may comprise a coil for use with magnetic resonance imaging. The sensor portion may be electrically connected by leads 11, only partly shown, to a remote module or modules (not shown) which incorporate the required power supply, signal detection and recording devices for data capture and transmission. Some or all of the modules to which the sensor is connected may be implanted within the body of the person receiving the graft, and incorporate appropriate means such as telemetry for transcutaneous data monitoring.

In a still further embodiment, shown in figure 7B, an external stent 1 comprises a fabric or porous structure 12 attached to several outer supporting members having the external appearance of linked rings or discs 13. For a portion of the stent, these outer members incorporate a sensor device 10a or series of sensors such as miniature radiofrequency and/or gradient coils for magnetic resonance imaging, or ultrasound transducers. The power supply for the sensors, excitation and data monitoring may be as in the figure 7A embodiment. Electrical wires 11 connect the sensor device 10a to the appropriate remote module or modules (not shown).

In other embodiments of an internal or external stent, the sensory action of the stent may derive from the construction of some or all of the supporting members which form the stent. In one such embodiment, the sensory action derives from a coil or coils of an electrically conducting material wound around the perimeter of the stent or interspersed at intervals along the stent which coil or coils may be excited by extracorporeal magnetic and/or electromagnetic fields, and the signal from the stent detected by magnetic coupling with an external detecting coil.

CLAIMS

1. A stent for supporting part of a blood vessel which stent includes a supporting portion around which or within which part of a blood vessel intended for grafting can be placed so that the stent internally or externally supports that part and the supporting portion of the stent is of a shape and/or orientation whereby flow between graft and host vessel is caused to follow a non-planar curve.
2. A stent as claimed in claim 1 wherein the supporting portion of the stent is fabricated to incorporate a non-planar curved form.
3. A stent as claimed in either preceding claim wherein the supporting portion is fabricated to incorporate a geometric arrangement of the junction between graft and host vessel whereby the tangent vector from the centreline of the graft does not intersect the centreline of the host vessel by consequence of an asymmetric disposition of the graft with respect to that host vessel at the junction with the graft.
4. A stent as claimed in any preceding claim which is of generally hollow tubular shape with three-dimensional curvature.
5. A stent as claimed in any one of claims 1 to 3 in the form of an open lattice generally tubular framework with discrete openings at each end thereof.
6. A stent as claimed in any preceding claim comprising a first supporting structure adapted to support or otherwise contact part of the vessel to be bypassed, with a secondary supporting structure extending away from the first supporting structure, but simultaneously capable of supporting the graft vessel part, said secondary structure

capable of maintaining a graft vessel part when located therein in non-planar curvature.

7. A stent as claimed in claim 6 wherein the secondary supporting structure comprises a plurality of elongate members linked in the region of their ends remote from the first supporting structure.

8. A stent as claimed in claim 6 or 7 wherein said elongate members define a curved section whose curvature is non-planar.

9. A stent as claimed in any preceding claim fabricated from shape memory alloy.

10. A stent as claimed in any preceding claim which is for use in supporting a graft vessel part internally, fabricated from a linked mesh or series of linked wire members which is coiled or partly coiled or helical or partly helical.

11. A stent as claimed in any preceding claim in combination with a device which assists in monitoring the condition of the host vessel and/or the graft.

12. A stent as claimed in claim 11 wherein the device is a sensor adapted to transmit a signal responsive to one or more internal flow conditions.

13. A stent as claimed in claim 12 in which the sensor is ring-shaped and is electrically connected to a remote module incorporating power supply, signal detection and recording means.

14. A stent as claimed in claim 12 or 13 wherein the sensor is adapted to transmit signals which can be monitored by ultrasound and/or magnetic resonance imaging and/or

electron spin resonance imaging techniques.

15. A stent as claimed in any one of claims 12 to 14 wherein the sensor portion forms an integral part of the stent and the means of excitation and signal detection are entirely extracorporeal.
16. A stent for supporting part of a blood vessel which stent includes a supporting portion around which or within which part of a blood vessel intended for grafting can be placed so that the stent internally or externally supports that part, in combination with at least one sensory device adapted to assist monitoring the condition of the graft and/or the vessel to be grafted.
17. A stent as claimed in claim 16 wherein the sensory device is adapted to transmit a signal responsive to one or more internal flow conditions within the grafted vessel part and/or within the vessel to be grafted.
18. A stent as claimed in claim 16 or 17 wherein the sensory device is ring-shaped and is electrically connected to a remote module incorporating power supply, signal detection and recording means.
19. A stent as claimed in any one of claims 16 to 18 wherein the sensory device is adapted to transmit signals which can be monitored by ultrasound and/or magnetic resonance imaging and/or electron spin resonance techniques.
20. A stent as claimed in any one of claims 16 to 19 wherein the sensory device forms an integral part of the stent and the means of excitation and signal detection are entirely extracorporeal.

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Fig. 1(a)

Fig. 1(b)

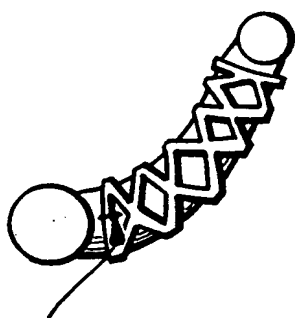
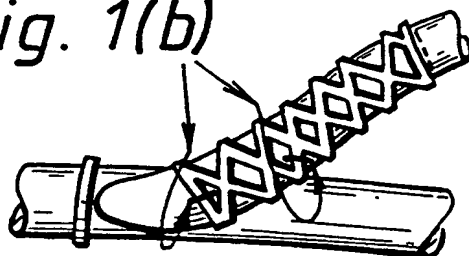
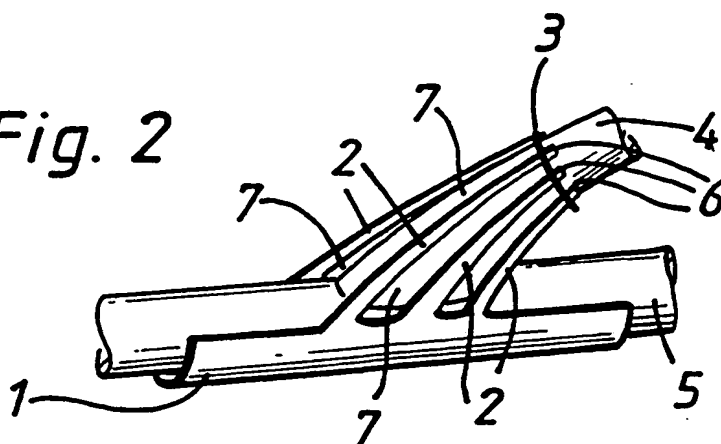


Fig. 1(c)

Fig. 2



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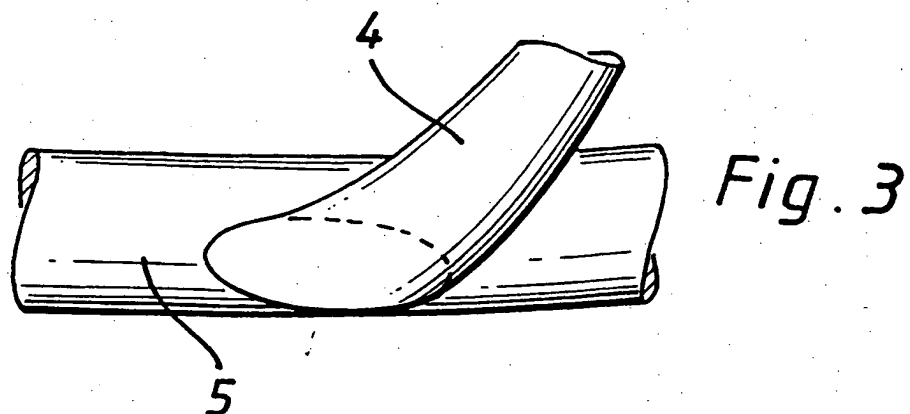


Fig. 3A

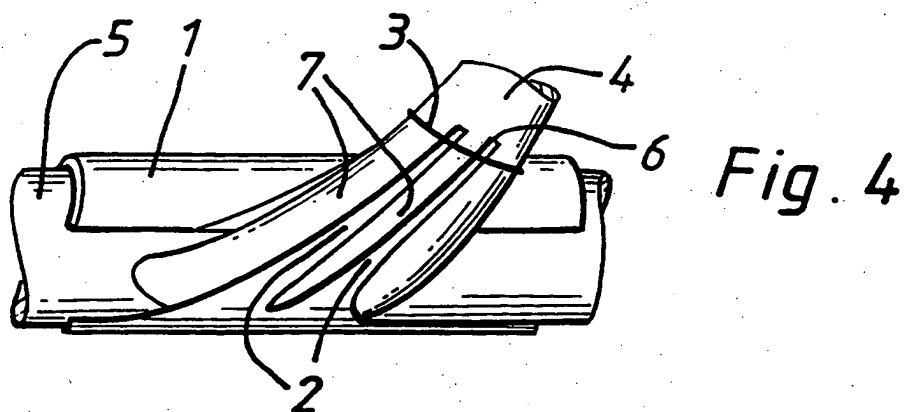
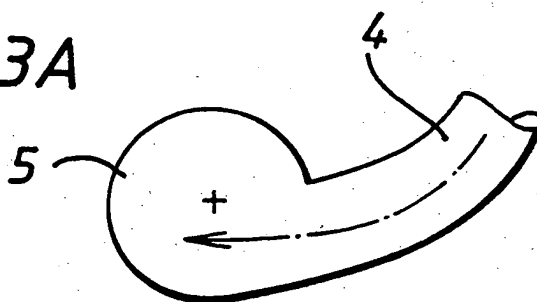
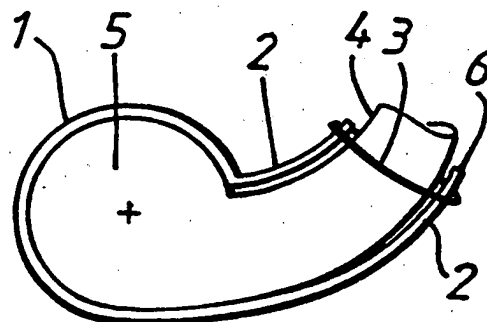


Fig. 4A



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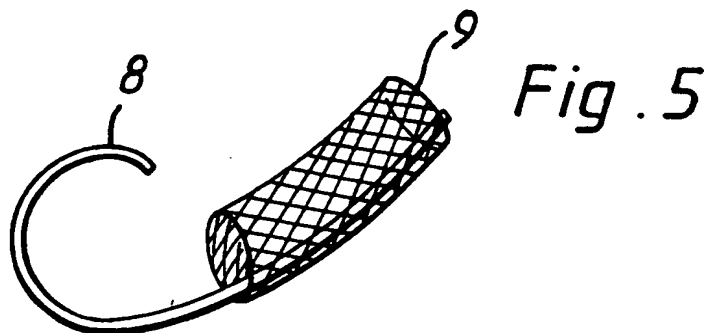


Fig. 6A

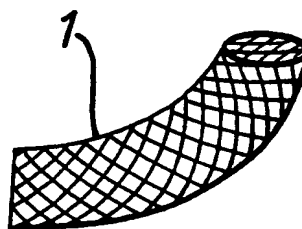


Fig. 6B

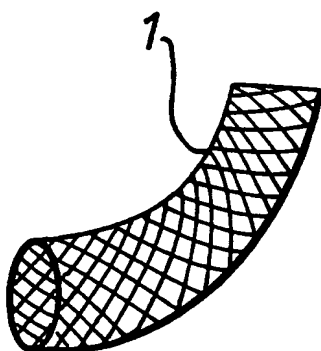
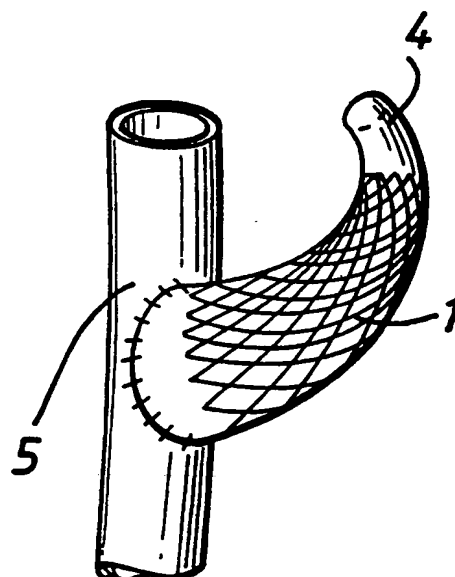


Fig. 6C



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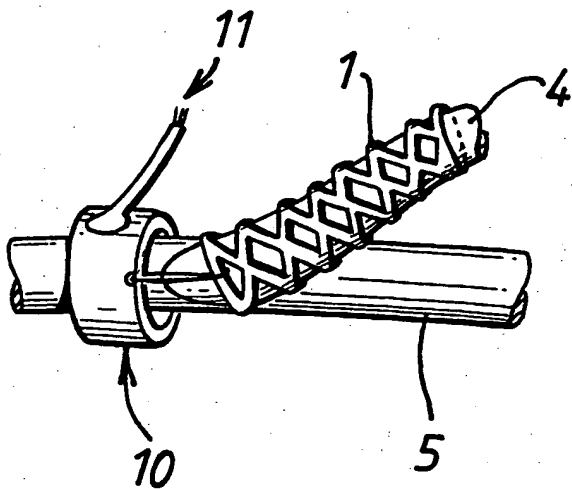


Fig. 7A

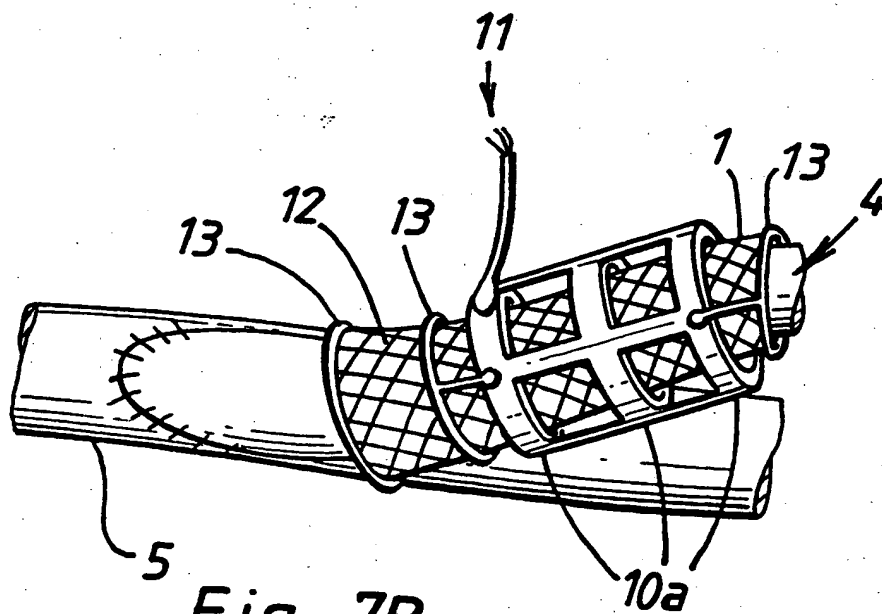
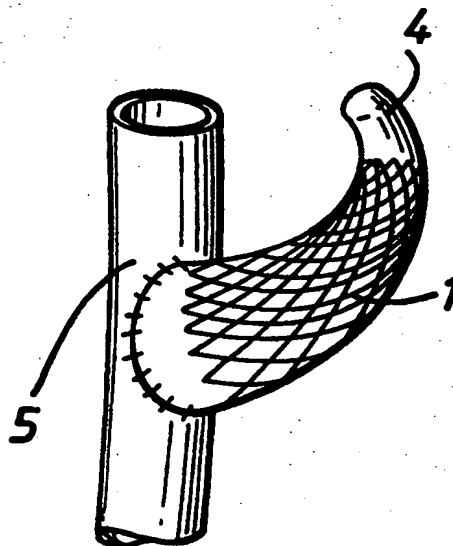


Fig. 7B

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(72) Inventors; and (75) Inventors/Applicants (for US only): DOORLY, Denis, Joseph [IE/GB]; 17 Clarence Road, Wimbledon, London SW19 8QF (GB). CARO, Colin, Gerald [GB/GB]; 7 Parkfields, Putney, London SW15 (GB). McLEAN, Mary, Anne [US/GB]; 15 Capell Road, Chorleywood, Rickmansworth WD3 5HY (GB).			
(74) Agent: MARCH, Gary, Clifford; Batchellor, Kirk & Co., 2 Pear Tree Court, Farringdon Road, London EC1R 0DS (GB).			

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/GB 98/01529

A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 95 14442 A (THE JOHNS-HOPKINS UNIVERSITY) 1 June 1995 see page 7, line 15 - page 8, line 16; figure 3	1
A	WO 95 09585 A (IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY & MEDICINE) 13 April 1995 see the whole document	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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Date of the actual completion of the international search

21 September 1998

Date of mailing of the international search report

23.12.1998

Name and mailing address of the ISA

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Smith, C

INTERNATIONAL SEARCH REPORT

International application No.

PCT/GB 98/01529

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
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because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

See annex

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-15

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

Multiple inventions:

1. Claims: 1-15
A stent for supporting part of a blood vessel intended for grafting with the supporting portion being of a shape to cause flow between graft and host vessel to follow a non-planar curve.
2. Claims: 16-20
A stent for supporting part of a blood vessel in combination with a sensor device adapted to assist in monitoring the condition of the blood vessel or graft.

INTERNATIONAL SEARCH REPORT

Information on patent family members

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